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(56) Opposing documents:

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(54) Controllable Sealing System for Catheter and Instrument Insertion Assemblies

In medical interventions in hollow organs, it has previously been a frequent practice to use thin-walled plastic tubes which are introduced into the hollow organ. If there is a difference in pressure between the external environment and the hollow organ, then problems arise which have previously been solved by using elastic, sliding seals, which however damage sensitive instruments or tissue parts to be removed.

An annular sealing sleeve of an elastic, or at least flexible, material is used as the seal here, said sealing sleeve sealing, constricting, or unsealing in an arbitrary manner the cross section to be sealed on filling of the interior of the sleeve with gaseous or liquid media.

A pneumatically or hydraulically controllable sealing sleeve makes it possible, to partially or completely seal, or also to completely unseal, as needed, the cross section of the connection between the hollow organ and the external environment, this fact in particular making it possible to use, without problems, even sensitive instruments in connection with a traditional sealing system in the form of the specified system.

DE 37 37 121 A1

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Description

In interventions of an operative or non-operative type in hollow organs or systems of hollow organs (for example, the vascular system) the problem frequently presents itself of introducing catheters or other instruments through an opening created by means of an incision or puncture. This presents no difficulties as long as the diameter of the instrument to be introduced is small, is of uniform size over its length, and the prevailing pressure difference between the interior of the punctured organ and the environment is not too large. However, it causes difficulties if the introduced instrument is to be removed from the organ and reinserted frequently, which, for example, becomes necessary when the size of the instrument is changed or when material is removed from the hollow organ.

In order to simplify these measures, it has previously been a routine practice to use so-called insertion assemblies or "sluices" which predominantly consist of a piece of very thin-walled plastic tubing which is laid into the desired hollow organ via a puncture and thus creates, between the interior and the external environment, a connection through which the catheter and necessary instruments can be introduced without difficulty. If, between the interior of the hollow organ and the external environment, there is a noteworthy pressure difference which should be maintained, then, at the outer end of the tube, a device providing sealing is mounted which is formed via a perforated or slotted rubber plate or a profiled elastomer part which is deformed and extended by the instrument guided through and lies tight on the device introduced (figure 2/7).

The disadvantages of such a seal are the following:

1. With the use of catheters or instruments with a very large diameter (e.g., balloon catheters for the dilation of the aortic valve) reliable sealing over the entire range of diameters (0 mm to ca. 6 mm diameter) often cannot be achieved.
2. If sensitive instruments or catheters have to be introduced into the tube through the seal, then the danger exists that they will be damaged or destroyed by the mechanical resistance which has to be overcome to deform the elastic seal (for example, guide wires on atherectomy catheters).
3. If tissue or foreign bodies are supposed to be removed from the hollow organs with the aid of catheters, then the danger exists that the bodies held on the catheter tip by low pressure or other holding mechanisms will be stripped off by the elastic seal and thus lost.
4. In interventions in the vascular system a layer of deposits from the blood coagulation system develops on the catheter shaft, depending on the time which the catheter remains within the vessel. These deposits are stripped off on removal of the catheter through the elastic seal, adhere in part to the seal, and on re-introduction of the devices through the seal are carried along into the vascular system, where they can be the cause of acute vascular occlusions.

The above-mentioned disadvantages of the systems used previously are avoided in the invention presented by several novel measures:

Alone or in addition to sealing of the sluice by an elastic sliding seal, a hydraulically (or pneumatically) adjustable sealing sleeve is introduced which allows the passage to be completely sealed or unsealed, or adapted to each instrument guided through, by filling or emptying the sleeve with liquid (or gases) from outside. Along with this, it is also possible by filling the sleeve at not too high pressure to achieve sealing along with easy displaceability of the catheter or instruments guided through.

In the case of combined use, the two sealing systems are mounted so as to be spatially separated from one another and are connected by a transparent chamber (figure 2/4). In this case, the sealing system controllable from outside is mounted on the chamber's side facing the hollow organ.

The connecting chamber is provided at each end with displaceable lateral connections which make it possible to rinse the chamber in order to afford an optimal view through its walls and to remove foreign bodies from the chamber by rinsing.

The transparent chamber is fastened by a connection to the controllable sealing system, where the connection can be released rapidly, without a tool, (figure 2/3) so that larger foreign bodies can be removed from the chamber without difficulty and other catheters (possibly with other chambers and seals) can be used. When the inner sealing system is closed, sensitive catheters can be guided, using a thin-walled tube to hold the sealing membrane open, through the external sealing system without disruption and without pressure equalization/blood loss. Thereupon, after removal of the tube to introduce the catheter, forward displacement into the hollow organ is possible without mechanical load of the tip by the inner seal opened in the meantime.

The size and form of the chamber, as well as the type and size of the second (external) seal, can be adapted to the planned application. Also during the procedure, the chamber with its second seal can be easily replaced by another without blood loss, pressure equalization, or the like occurring with a blocked inner seal.

Through the construction of the inner seal it is ensured that tissue or materials which are supposed to be removed from the hollow organ by means of the catheter or the like are not stripped off of the catheter by the seal and thus lost. This is achieved by the interior of the extensible sleeve being pressurized with a low pressure, the sleeve lying tightly on the inner wall of the sluice body following the pressure gradient, and thus the full cross section being unsealed (figure 1a).

The cross section, length, and form of the sealing sleeve can be chosen according to the requirements. Depending on the cross section to be sealed, one or more chambers are provided, which are to be filled simultaneously or separately from one another. The sealing sleeve is made of an extensible, soft, and flexible but tear-resistant material (natural or synthetic rubber or soft plastic, possibly reinforced by textile).

Claims

1. Sealing system, e.g., for sealing insertion assemblies or "sluices," which makes possible variable sealing which can be controlled from outside, hydraulically or pneumatically, characterized by the fact that a sealing sleeve is used through whose pressurization with low pressure the cross section to be sealed is unsealed (figure 1a) in order, for example, to introduce sensitive instruments into or to take samples from the hollow organ in question. If the sleeve is put under excess pressure, then it seals the cross section remaining free either completely (figure 1b) or lies tightly against instruments guided through and thereby causes a seal (figure 1c).

2. Sealing sleeve according to claim 1, characterized by the fact that it is made of a natural or synthetic rubber or soft plastic, possibly reinforced by textile.

3. Sealing sleeve according to claims 1 and 2, characterized by the fact that it has a chamber (figure 1a – 1c).

4. Sealing sleeve according to claims 1 and 2, characterized by the fact that it has several chambers (for example, figure 1d).

5. Sealing sleeve according to claims 1 and 2 and one of claims 3 to 4, characterized by the fact that it is mounted as a single seal at the end of an insertion assembly or similar instrument.

6. Sealing sleeve according to claims 1 and 2 and according to one of claims 3 to 4 characterized by the fact that it is mounted in connection with a second seal (perforated or slotted membrane or second sealing membrane) at the end of an insertion assembly or similar instrument (for example, figure 2).

7. Sealing system according to claim 6, characterized by the fact that the connection between the two seals is produced by a transparent chamber (figure 2/4) which has lateral connections at both ends (figures 2/5 and 2/6) which make possible the rinsing of the interior with transparent liquids and the rinsing out of impurities, blood, thromboses, and so on.

8. Sealing system according to claim 6 or claim 7, characterized by the fact that there is at least one tight connection, easily removable without a tool, between the connecting chamber and one or both seals, said connection making possible rapid removal, replacement, or cleaning of the connecting chamber (figure 2/3) while the insertion assembly (blocked with a controllable seal) is still located in the hollow organ to be examined or treated.

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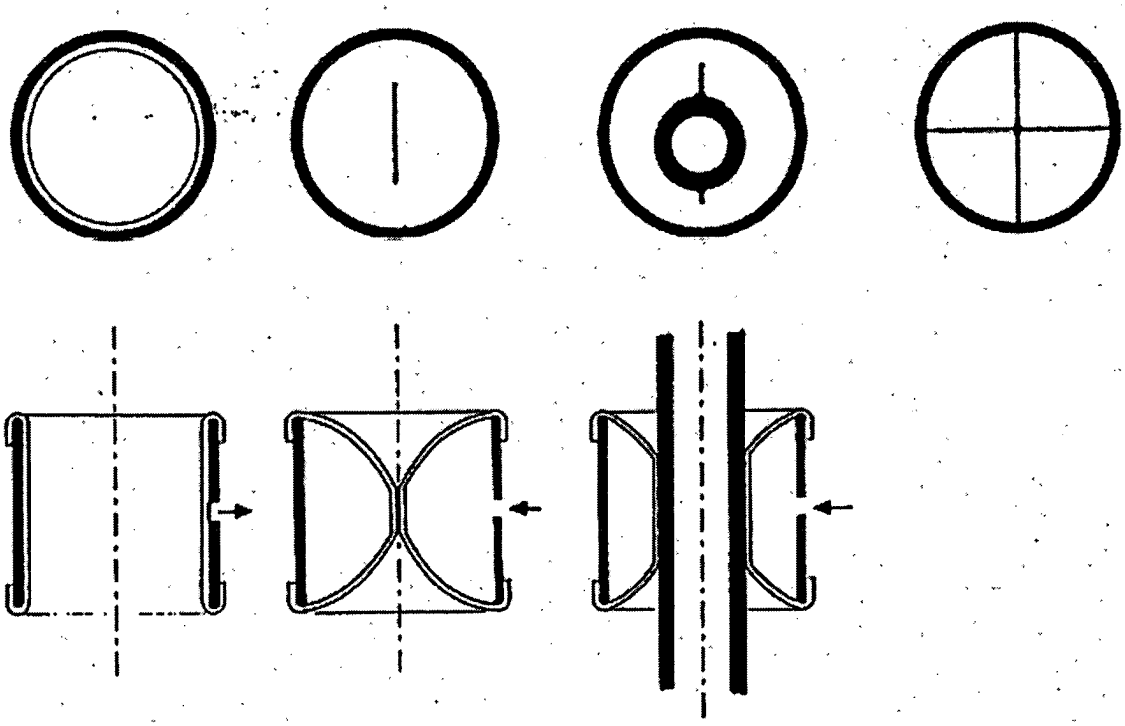

Figure 1a Figure 1b Figure 1c Figure 1d

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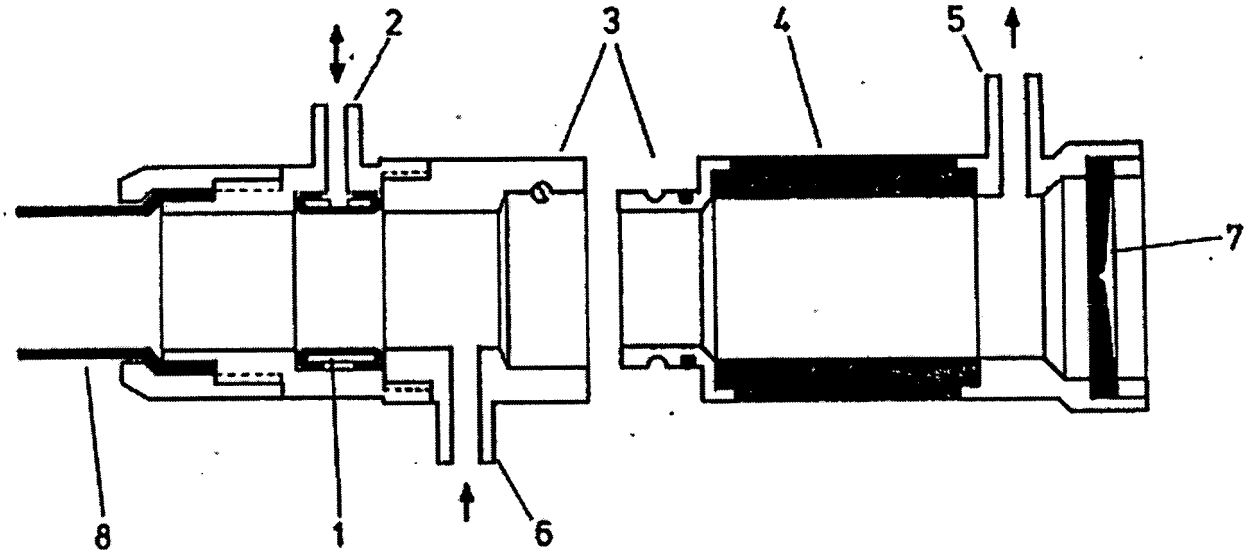

Legend for figure 2:

1 - controllable sealing sleeve

2 - connection for the control of the unsealed cross section via filling/emptying with gases or liquids

3 - rapidly releasable connection between both sealing systems

4 - transparent connecting chamber

5 - lateral connection for rinsing of the connecting chamber

6 - lateral connection for rinsing of the connecting chamber

7 - elastic sliding seal

8 - insertion assembly's tube introduced into the body